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SEP 25 2000

OLSON & HIERL, LTD  
20 NORTH WACKER DRIVE  
36TH FLOOR  
CHICAGO IL 60606

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,949,718

Dear Mr. Hierl:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,949,718 for a period of 605 days.

While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The communication to FDA should include sending a copy of the certificate of extension to New Drug Application and another copy of the certificate of extension to Mary Ann Holovac, who will update the Orange Book. Mary Ann's address is

CDER OIT DDMS  
NLRC 235 (HFD-090)  
5516 Nicholson Lane  
Kensington, MD 20895

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Kam Trip

Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: David T. Read Re: ThermoChoice™ Uterine Balloon Therapy System  
Acting Director Regulatory Policy Staff, CDER FDA Docket No. 98E-0850  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

# UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

PATENT NO. : 4,949,718  
ISSUED : August 21, 1990  
INVENTORS : Robert S. Neuwirth, et al.  
PATENT OWNER : Gynelab Products  
PRODUCT : ThermaChoice™ Uterine Balloon Therapy System

This is to certify that an application under 35 U.S.C. § 156 has been filed in the U.S. Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,949,718 based upon the regulatory review of the product ThermaChoice™ Uterine Balloon Therapy System by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

605 days

from September 9, 2008, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the U.S. Patent and Trademark Office to be affixed this 12th day of September 2000.

A handwritten signature in cursive script, appearing to read "Q. Todd Dickinson".

Q. Todd Dickinson

Under Secretary of Commerce for Intellectual Property  
and Director of the United States Patent and  
Trademark Office